UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated, **Plaintiff,** **v.** **ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, ASTRAZENECA AB, and AKTIEBOLAGET HASSLE,** **Defendants.**	**Civil Action No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, a wholesaler/distributor of pharmaceutical products, on behalf of itself and the class defined below (the "Class"), brings this antitrust action against Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle (collectively "AZ" or "Defendants"), and alleges as follows based upon personal knowledge as to matters relating to itself, and upon the investigation of its counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from AZ's unlawful, anticompetitive scheme to block the entry of generic competition and thereby to illegally maintain its monopoly power in the United States market for extended-release metoprolol succinate, which market is comprised of the pharmaceutical AZ sells under the brand name Toprol-XL, plus its AB-rated generic equivalents. AZ's scheme allowed it to charge supracompetitive prices, prevented prices of extended-release metoprolol succinate from falling to the competitive level that would have been reached subsequent to the entry of generic competition, and thereby caused Plaintiff and members of the Class to pay overcharges on their purchases of extended-release metoprolol succinate.

2. Toprol-XL is an extended-release drug approved by the U.S. Food & Drug Administration ("FDA") for treating hypertension, angina, and congestive heart failure (together, herein referred to as "heart disease"). AZ sells this drug in 25 mg, 50 mg, 100 mg, and 200 mg dosages.

3. As alleged in greater detail herein, Defendants engaged in a scheme involving the commission of fraud and/or inequitable conduct before the United States Patent and Trademark Office ("PTO") in order to obtain two patents – U.S. Patent No. 5,001,161 (the "'161 Patent") and U.S. Patent No. 5,081,154 (the "'154 Patent") (collectively, the "Patents") – which, in the absence of such conduct, would not have issued. Defendants then proceeded to improperly procure the objectively baseless listing of the Patents with the FDA, in the FDA's so-called "Orange Book," in order to assert sham patent infringement claims against, and to block the market entry of, any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of Toprol-XL.

4. In July and August of 2003 and April and December of 2004, Defendants did, in fact, institute litigation against companies seeking approval from the FDA to market generic forms of Toprol-XL (the "Patent Litigation"), even though Defendants knew that the Patents had been improperly procured, were invalid, that no reasonable claim of infringement could be asserted against said companies based upon them, and that the listing of the Patents with the FDA was objectively baseless. In other words, the Patent Litigation was objectively baseless, "sham" litigation. Defendants instituted the Patent Litigation not for any legitimate purpose, but solely because they knew the mere filing of such litigation would automatically delay the FDA's granting of final marketing approval to the generic manufacturers, without which approval the generics cannot come to market.

5. In connection with their objectively baseless listings of the Patents with the FDA and in filing the objectively baseless Patent Litigation, Defendants illegally and intentionally manipulated certain provisions of the 1984 amendments to the Food, Drug, and Cosmetic Act added by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act or Hatch-Waxman Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)). As many courts have recognized, these amendments were principally designed to streamline the process by which generic drugs are brought to market.

6. Defendants knew and intended that under the Hatch-Waxman Amendments the *mere filing* of the Patent Litigation would automatically bar the FDA from granting marketing approval to any of the would-be competing generic companies for up to thirty months, even though the Patents were fraudulently obtained and the Patent Litigation was baseless. Thus, although the Patents were ultimately found to be invalid, unenforceable, and procured through inequitable conduct by a United States District Court, Defendants were nevertheless able to block generic competition for an extended period of time and unlawfully maintain their monopoly simply by listing their Patents in the Orange Book and then filing and pursuing baseless patent litigation in the federal courts.

7. By their unlawful acts, Defendants have willfully and unlawfully maintained their monopoly power over Toprol-XL and its AB-rated generic equivalents, *i.e.* the extended-release metoprolol succinate "molecule," and thereby benefitted from hundreds of millions of dollars in ill-gotten revenues.

8. Absent Defendants' unlawful conduct, less expensive, bioequivalent generic versions of Toprol-XL would have been on the market much earlier. Through their unlawful conduct,

Defendants illegally deprived Plaintiff (and other entities that purchased Toprol-XL directly from AZ, who comprise the Class more specifically defined below) of access to substantially lower-priced extended-release metoprolol succinate. More specifically, through their unlawful conduct Defendants have illegally deprived Plaintiff and other Class members of the ability to sooner (a) substitute purchases of less-expensive generic versions of Toprol-XL for their purchases of far-more-expensive branded Toprol-XL, (b) receive discounts on their remaining purchases of branded Toprol-XL, and (c) purchase generic extended-release metoprolol succinate at lower prices. Defendants have caused Plaintiff and the Class to overpay for extended-release metoprolol succinate by at least hundreds of millions of dollars.

9. The overcharges that purchasers of Toprol-XL were forced to pay by Defendants' unlawful conduct constitute prototypical antitrust injury.

10. As a result of Defendants' unlawful, anticompetitive scheme, Defendants have (1) unreasonably restrained, suppressed, and eliminated competition in the market for extended-release metoprolol succinate (Toprol-XL and its AB-rated generic equivalents); (2) illegally maintained monopoly power in the market for extended-release metoprolol succinate; (3) fixed, raised, maintained, and/or stabilized the price of extended-release metoprolol succinate at supra-competitive levels; and (4) overcharged Plaintiff and other Class members by hundreds of millions of dollars by depriving them of the benefits of competition from lower priced generic versions of Toprol-XL

11. Defendants possess monopoly power with respect to extended-release metoprolol succinate, which power was maintained through willful and illegal conduct, and not through growth or development as a consequence of a superior product, business acumen or historic accident.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

13. Venue is proper in this judicial district under 28 U.S.C. § 1391 and 15 U.S.C. § 15(a) and/or 15 U.S.C. § 22, because Defendants transact business, committed an illegal or tortious act, have an agent, and/or are found within this District, and/or a because substantial portion of the events described below have been carried out in this District.

PARTIES

14. Plaintiff Rochester Drug Co-operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with a principal place of business located at 50 Jet View Drive, Rochester, New York, 14624.

15. During the Class Period, as defined below, RDC purchased Toprol-XL directly from one or more of the Defendants.

16. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, which distributes, markets, sells, and/or profits from pharmaceutical products including Toprol-XL throughout the United States. Its U.S. corporate headquarters is located at 1800 Concord Pike, Wilmington, DE. AstraZeneca Pharmaceuticals LP is a U.S. subsidiary of AstraZeneca PLC, and was created as a result of the union of Zeneca Pharmaceuticals and Astra Pharmaceuticals LP in the U.S. after the 1999 merger.

17. Defendant AstraZeneca LP is a limited partnership organized and existing under the laws of Delaware, with its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration

("FDA") for metoprolol succinate preparations with extended-release, which it sells under the brand name Toprol-XL. AstraZeneca LP is a U.S. subsidiary of AstraZeneca PLC.

18. Defendant AstraZeneca AB is a corporation organized and existing under the laws of Sweden, having its principal place of business at S 151 85 Sodertalje, Sweden.

19. Defendant Aktiebolaget Hassle is a corporation organized and existing under the laws of Sweden, having its principal place of business at Molndal, Sweden. Aktiebolaget Hassle is a wholly-owned subsidiary of AstraZeneca AB.

20. Defendants' actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

INTERSTATE TRADE AND COMMERCE

21. During all or part of the Class period (defined below), one or more Defendants manufactured and sold substantial amounts of Toprol-XL in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

22. At all material times, Toprol-XL manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

23. During all or part of the Class period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Toprol-XL.

24. In furtherance of their efforts to maintain monopoly power over Toprol-XL and its generic equivalents wilfully, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

25. Defendants' efforts willfully to maintain monopoly power over Toprol-XL and its generic equivalents wilfully, as alleged herein, have substantially affected interstate and foreign commerce.

CLASS ALLEGATIONS

26. Plaintiff brings this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and the following class:

> All persons and entities in the United States who purchased Toprol-XL directly from Defendants at any time from May 5, 2005 through the present and continuing until the effects of Defendants' anticompetitive conduct cease (the "Class Period"). Excluded from the class are Defendants and their parents, employees, subsidiaries, and affiliates (the "Class").

27. The Class is so numerous that joinder of all members is impracticable. Plaintiff believes that the Class numbers one hundred or more.

28. There are numerous questions of law and/or fact common to the Class, including:

a. whether Defendants willfully obtained and/or maintained monopoly power over Toprol-XL and its generic equivalents;

b. whether Defendants' Patents were obtained through fraud and/or inequitable conduct;

c. whether but for Defendants' fraud, the Patents would not have issued;

d. whether Defendants' listings of the Patents in the FDA "Orange Book" were objectively baseless;

e. whether the Patent Litigation was objectively baseless;

f. whether Defendants maintained monopoly power by delaying generic entry;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

h. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

i. whether, and to what extent, Defendants' conduct caused antitrust injury in the nature of overcharges to Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

29. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

30. Plaintiff's claims are typical of the claims of the Class because all Class members paid overcharges, and thus suffered antitrust injury, as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

31. Plaintiff will fairly and adequately represent, and protect the interests of, the Class. Plaintiff has retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiff has no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

32. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

BACKGROUND

A. Branded Drugs

33. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (the "FD&C Act") regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FD&C Act, approval by the FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

34. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents, plus any extension of the original patent granted pursuant to the Hatch-Waxman Act.

35. Pursuant to 21 U.S.C. § 355(b), in its NDA, the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

36. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders

from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

37. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, so as to force generic manufacturers to file what, as described below, is commonly known as a Paragraph IV certification.

38. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information").

39. As a result, as numerous courts have recognized, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

B. Generic Drugs

40. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand name drug.

41. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics of that particular molecule enter the market.

42. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

43. To obtain FDA approval of an ANDA (and thus the legal right to sell a generic version of brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA does not infringe any patent listed in the Orange Book as claiming the brand-name drug.

44. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Four types of certifications are available:

I. The brand name manufacturer has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

45. If a drug manufacturer's ANDA contains certifications under Paragraphs I, II or III, the ANDA may be filed five years after the NDA for the referenced drug was approved. If the ANDA contains a paragraph IV certification, the ANDA can be filed 4 years after the NDA for the

referenced drug was approved. *See* Frequently Asked Questions for New Product Exclusivity at www.fda.gov/cder/about/smallbiz/exclusivity.htm

46. If a generic manufacturer files a Paragraph IV Certification asserting that the patent is invalid or will not be infringed, the brand-name manufacturer has the opportunity to delay the generic manufacturer's receipt of final approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue.

47. The Paragraph IV Certification constitutes a "technical act of infringement" under Hatch Waxman which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

48. Because of this thirty-month stay, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand company's ever having to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry. Indeed, as a practical matter the brand name company wins the lawsuit simply by filing it, as it automatically protects its monopoly for up to two-and-a-half years, and possibly longer, while the infringement action winds its way through the court system. (And the brand name company has an incentive to stall the progress of this

action.) There are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

49. An improper Orange Book listing also has additional anticompetitive effects, because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period is awarded to the first Paragraph IV Certification ANDA filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously.

50. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act.

DEFENDANTS' ANTICOMPETITIVE CONDUCT

51. AZ has successfully forestalled generic competition to Toprol-XL from entering the market – thereby delaying purchasers the benefits of cheaper, generic extended-release metoprolol succinate products – by obtaining the Patents, which they did not deserve, from the PTO through intentional and fraudulent misrepresentations and omissions, fraudulently listing the Patents in the Orange Book, and bringing and maintaining the sham Patent Litigation based thereon.

A. Defendants' Fraudulent Procurement of Patents

52. Defendants have falsely asserted that two patents cover Toprol-XL and bar generic competition: the '161 Patent and the '154 Patent.

53. The '161 Patent issued on March 19, 1991, with a single claim: "A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier."

54. The '154 Patent issued on January 14, 1992, with a single claim: "Metoprolol succinate."

55. The named inventors on both the '161 and '154 Patents are Curt H. Appelgren and Eva C. Eskilson. However, Appelgren and Eskilson were not the inventors of metoprolol succinate, which had been first made at AZ before either of them joined the company and more than ten years before patent applications claiming the compound were filed in the PTO naming them as inventors.

56. As explained in detail below, when Appelgren and Eskilson tried to claim formulations of metoprolol succinate for their new employer after leaving the employ of AZ, AZ contested their right to do so and asserted its ownership to rights to metoprolol succinate in a complaint filed in the Swedish Patent Office that alleged that metoprolol succinate had been invented by its employee Toivo Nitenberg and disclosed in confidence to Appelgren and Eskilson. Several months later, Appelgren and Eskilson agreed to drop metoprolol succinate from their application, assign rights to AZ, and file a new application directed to metoprolol succinate and assign the new application to AZ.

57. In the early 1980s, Appelgren and Eskilson were employed at AZ's AB Hassle division in Molndal, Sweden. Among their duties, Appelgren and Eskilson participated in a project

to develop new controlled-release formulations of metoprolol. Their duties, however, had nothing to do with the identification, synthesis, or invention of different salts of metoprolol.

58. Under the organization and procedures within the AZ organization at the time, responsibility for synthesis of alternative compounds rested with a group employed by Astra Pharmaceutical Production AB, located in Sodertalje, Sweden. Neither Appelgren nor Eskilson conceived of or synthesized metoprolol succinate. Rather, that compound was supplied to the group of which Appelgren and Eskilson were members by chemists employed by AZ in Sodertalje, including Lars Lilljequist.

59. In his deposition taken in AZ's patent litigation against potential generic competitors, Appelgren admitted that metoprolol succinate was not a newly developed product at AZ, but was an "old," known compound supplied to the product development group.

60. The other inventor, Ms. Eskilson, could not recall at her deposition why she was named an inventor of metoprolol succinate.

61. At the end of 1982, Appelgren resigned from Hassle to form his own company, Lejus Medical AB ("Lejus"). Appelgren was a founder and 25% owner of Lejus.

62. Several months later, Eskilson joined Appelgren at Lejus, and Appelgren and Eskilson began to work on developing a sustained release formulation of quinidine sulphate for a U.S. company unrelated to AZ.

63. On January 10, 1984, Lejus filed a Swedish patent application (SE8400085, the "Swedish Application") naming Appelgren and Eskilson as the inventors based on the sustained release formulation they had developed for quinidine sulphate at Lejus. When listing potentially useful pharmaceutical agents for their sustained release formulation, Appelgren and Eskilson included metoprolol succinate. Although Appelgren and Eskilson knew of metoprolol succinate

from their work at Hassle, they did not believe they were violating any duty of confidentiality by disclosing it in the Swedish Application because they did not believe it was a new compound and certainly did not believe they were its inventors.

64. The Lejus application was published in July of 1985 and came to the attention of Hassle and its parent, Astra AB, which on October 21, 1985, filed a complaint with the Swedish Patent Office asserting that Appelgren and Eskilson were not the inventors of metoprolol succinate and that the compound was invented by Toivo Nitenberg, a Hassle employee. At this point, Lejus had already filed a corresponding U.S. patent application (U.S. Serial No. 690,197 (the "'197 Application")), which ultimately issued as U.S. Patent No. 4,780,318 (the "'318 Patent").

65. To settle Hassle's complaint, Lejus, Appelgren, and Eskilson agreed to assign Hassle any rights to metoprolol succinate in an agreement dated April 21, 1986 (the "Lejus/Hassle Agreement"). The Lejus/Hassle agreement was negotiated on behalf of Hassle and AZ at least by employees of AZ's patent department, including Bengt Wurm.

66. In March of 1988, Lejus filed the U.S. patent application (U.S. Serial No. 172,897 (the "'897 Application")) that eventually issued as the '161 Patent, tracking almost exactly the agreed-upon language from the Lejus/Hassle agreement. Thereafter, Lejus assigned this application to Hassle.

67. By the time this application was filed in March of 1988, more than one year had passed since publication of Lejus's Swedish Application naming metoprolol succinate and claiming sustained-release pharmaceutical formulations containing metoprolol succinate. Thus, Hassle knew that unless the applications issuing as the '161 and '154 Patents could rely on the filing date of the Swedish Application, any new claims in the '161 and '154 Patents to metoprolol succinate or sustained-release formulations of it would be unpatentable, *inter alia*, as anticipated by the Swedish

Application, pursuant to 35 U.S.C. §§ 102(b), 119(a). They would have been unpatentable as anticipated because of other prior art as well, including an article published in 1987 and two other patent applications filed by Hassle.

68. Thus, Hassle knew that if it identified Nitenberg as the inventor of the '161 and '154 Patents, then because Nitenberg is not an inventor on the '897 application and the Swedish Application, that Hassle would not be able to rely on the filing date of the Swedish Application for the '161 and '154 Patents and those patents would be rejected by the PTO or invalidated in litigation.

69. Hassle knew that in order to obtain U.S. patents directed to metoprolol succinate and avoid the bar of the published Swedish Application, it had to file fraudulently in the names of Appelgren and Eskilson in order to make a (fraudulent) claim of priority. Hassle did just this.

70. Appelgren, Eskilson, the representatives prosecuting the applications, employees of Hassle and AZ, and others involved in the prosecution of the '161 and '154 Patents knew that Appelgren and Eskilson were not the joint inventors of metoprolol succinate or the subject matter claimed in the Patents.

71. During the prosecution of the '161 and '154 Patents, Defendants did not disclose to the PTO its complaint to the Swedish Patent Office dated October 21, 1985, the Lejus/Hassle Agreement, the facts leading to these documents, or that Toivo Nitenberg had made metoprolol succinate in 1971.

72. During the prosecution of the '161 and '154 Patents, Defendants intentionally made other material misrepresentations and omissions, including in submitting a declaration of an employee, John Anders Sandberg (the "Sandberg Declaration"). Among other things, although the Sandberg Declaration extols the virtue of metoprolol succinate for use in once-daily, controlled-

release preparations, Defendants did not explain that its alleged virtues were unique to a particular formulation developed by Sandberg, unrelated to any work done by Appelgren and Eskilson. The Sandberg Declaration also omits material information known to Dr. Sandberg and Defendants about prior art and the performance of other metoprolol salts.

73. Because the facts and information that Defendants failed to disclose and/or misrepresented to the PTO directly relate to proper inventorship and derivation and would have precluded patentability under, at least, 35 U.S.C. § 102(f), they were of the highest materiality.

74. These omissions and/or misrepresentations were purposeful. They were made with an intent to deceive and did, in fact, deceive the PTO, resulting in the issuance of the '161 and '154 Patents.

B. Defendants' Sham Disclaimer

75. Claim 8 of Defendants' '318 Patent, which issued on October 25, 1988 (expiring on October 25, 2005), claims, among other compounds, "metoprolol succinate."

76. The claims of the '161 and '154 Patents also claim "metoprolol succinate," but are due to expire on March 18, 2008, which is more than 17 years after the issuance of the '318 Patent.

77. Defendants knew that the Patent Act (as it existed when the '318 Patent was filed) entitled them only to 17 years of patent protection for metoprolol succinate and that the Patent Act prohibited them from "double patenting" metoprolol succinate in order to obtain more than 17 years of patent protection. However, Defendants did not file any terminal disclaimers limiting the patent monopoly for metoprolol succinate to 17 years.

78. Because Defendants did not file terminal disclaimers for the '161 and '154 Patents, the Patents are invalid for obviousness-type double patenting due to Claim 8 of the '318 Patent, and Defendants knew this.

79. On November 21, 2003, Defendants filed a statutory disclaimer of Claim 8 of the '318 Patent, effectively canceling the claim. By filing the statutory disclaimer of Claim 8 of the '318 Patent, instead of filing terminal disclaimers of the '161 and '154 Patents, Defendants wrongfully and in bad faith attempted to circumvent double-patenting invalidity of the '161 and '154 Patents and obtain more than 17 years of patent protection for metoprolol succinate.

80. Defendants' filing of the statutory disclaimer of Claim 8 to overcome the obviousness-type double patenting invalidity of the '161 and '154 Patents is objectively baseless and was not done for any legitimate purpose. This filing was, thus, a sham.

C. Defendants' Sham Orange Book Listings

81. Despite Defendants' knowledge that the '161 and '154 Patents were invalid, Defendants caused the patents to be listed in the Orange Book as covering Toprol-XL and as reasonably giving rise to a claim of infringement. Further, Defendants did not withdraw these Orange Book listings even after being provided with clear proof that they were improper. The Orange Book listings were objectively baseless.

82. Defendants knew that under the Hatch-Waxman Act, if they sued to enforce patents listed in the Orange Book, they would (a) receive effectively an automatic injunction that would last up to thirty months, or more, (b) bar generic competitors from marketing extended-release metoprolol succinate products without any proof of likelihood of success, and regardless of the invalidity of the listed patents or the baselessness of the suit, and (c) delay FDA action, attention to, and approval of ANDAs filed by generic competitors.

83. Defendants' decisions to cause the patents to be listed, not to inform the FDA that the '161 and '154 Patents were invalid, and not to withdraw the Orange Book listings, were intentionally deceptive.

D. Defendants' Sham Patent Litigation

84. Despite Defendants' knowledge that the '161 and '154 Patents were invalid, Defendants commenced the Patent Litigation based on these Patents against the following companies seeking to market bioequivalent, generic versions of Toprol-XL: KV Pharmaceutical Co., Andrx Pharmaceuticals, LLC, Andrx Corp., and Eon Labs, Inc. (collectively, the "Generic Manufacturers"). The Patent Litigation was ultimately transferred to the United States District Court for the Eastern District of Missouri for pretrial proceedings.

85. Knowing that the Patent Litigation was objectively baseless and a sham, Defendants nonetheless commenced and maintained them deceptively, in bad faith, and with the specific intent and subjective motivation to prevent the Generic Manufacturers from selling competing extended-release metoprolol succinate products.

86. Defendants knew that even though ultimately they could not expect success on the merits of the Patent Litigation, the process itself of commencing the sham litigation would nonetheless enable them automatically to bar the generic manufacturers from coming to market for up to thirty months or more, under 21 U.S.C. § 355(j)(5)(b)(iii).

87. Defendants' lawsuits were shown to be a sham. On January 17, 2006, United States District Judge Rodney W. Sippel granted summary judgment for the Generic Manufacturers, determining, *inter alia*, any reasonable jury was bound to find that clear and convincing evidence established that (1) the '161 and '154 Patents were invalid for double-patenting based on Claim 8 of the '318 Patent, and (2) the '161 and '154 Patents were unenforceable because of AZ's

misconduct in not informing the patent examiner about the dispute regarding inventorship while prosecuting the patents. On the latter point, Judge Sippel found that the inventorship issue was "highly material" to patentability and that AZ's intent to deceive was "clearly present."

88. Defendants' conduct during the Patent Litigation further evinces their anticompetitive intent. For example, Judge Sippel noted that, during the litigation, Defendants "maintained a pattern of submitting witness declarations that contradict their own prior deposition testimony."

EFFECTS ON COMPETITION

89. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Toprol-XL without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Toprol-XL much sooner than they actually will be marketed, and, at all events, would have been on the market no later than May 5, 2005.

90. The generic manufacturers seeking to sell generic Toprol-XL have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products. Eon Labs, Inc. ("Eon"), for example, has a history of achieving high approval rates for its ANDAs, usually within twelve to thirteen months of filing an ANDA.

91. Eon has publicly affirmed its intention and ability to begin selling generic Toprol-XL upon approval of its ANDA. However, Defendants' unlawful conduct has caused the ANDA approval process to be delayed by the FDA, and caused the generic manufacturers to divert resources from their ANDA applications and to expend unnecessary resources on litigation. Another potential generic manufacturer, Andrx, has recently had its pending drug applications placed on

hold, which would not have affected its extended-release metoprolol succinate ANDA absent Defendants' causing delay.

92. Absent the Patent Litigation, which imposed an automatic thirty-month stay of final ANDA approval, the Generic Manufacturers and the FDA would have had reason to, and would have, focused upon and poured resources into the ANDA approval process for generic extended-release metoprolol succinate. Such focus and resources would have brought far earlier FDA approval and far earlier marketing of generic Toprol-XL.

93. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Toprol-XL caused Plaintiff and the Class to pay more than they would have paid for extended-release metoprolol succinate, absent Defendants' illegal conduct.

94. Typically, generic versions of brand-name drugs are initially priced significantlybelow their corresponding, AB-rated brand-name versions. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand-name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

95. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiff, would have paid less for extended-release metoprolol succinate by (a) substituting purchases of less-expensive AB-rated

generic extended-release metoprolol succinate for their purchases of more-expensive branded Toprol-XL, (b) receiving discounts on their remaining branded Toprol-XL purchases, and (c) purchasing generic extended-release metoprolol succinate at lower prices sooner.

96. Moreover, because of Defendants' objectively baseless Orange Book listings, once the generic manufacturer that filed first for a particular dosage strength begins to sell its generic version of Toprol-XL, it will be entitled to 180 days of generic marketing exclusivity for that dosage strength. This process delays the entry of other generic competitors into the market and further forestalls price competition, competition that would have existed but for Defendants' wrongful conduct.

97. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Toprol-XL.

98. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT UPON PLAINTIFF AND MEMBERS OF THE CLASS

99. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Toprol-XL from Defendants. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their extended-release metoprolol succinate requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Toprol-XL was artificially inflated by Defendants' illegal conduct and/or (2) class members were deprived of the opportunity to purchase lower-priced generic versions of extended-release metoprolol succinate sooner.

100. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

MONOPOLY POWER

101. Defendants have monopoly power over Toprol-XL and its generic equivalents, because they have had the power to maintain the price of Toprol-XL at supracompetitive levels profitably, without losing substantial sales.

102. A significant, non-transitory price increase by Defendants of Toprol-XL would not have caused a significant loss of sales to other products.

103. Defendants need to control only Toprol-XL and its AB-rated generic equivalents in order to maintain the price of Toprol-XL profitably at supracompetitive prices. So while the market entry of a competing, AB-rated generic version of Toprol-XL will render Defendants unable to maintain their current prices of Toprol-XL without losing substantial sales, the existence of or entry onto the market of no other drug product on the market would render Defendants so unable.

104. Defendants also sold Toprol-XL at prices well in excess of marginal costs and enjoyed high profit margins.

105. Moreover, Defendants have had, and exercised, the power to exclude competition.

106. To the extent that defining a relevant product market is necessary in this case, the relevant product market is Toprol-XL and its AB-rated generic equivalents.

107. The relevant geographic market is the United States.

108. Defendants currently hold a 100% share in the relevant product market in the United States.

109. Plaintiff and members of the Class continue to pay higher prices for their extended-release metoprolol succinate purchases than they would otherwise have paid, as a result of Defendants' unlawful and willful acquisition and/or maintenance of their monopoly power through the conduct alleged herein.

FIRST CLAIM FOR RELIEF

Anticompetitive Scheme Under Section 2 of the Sherman Antitrust Act

110. Plaintiff incorporate by reference the preceding allegations.

111. Defendants knowingly and intentionally engaged in an anticompetitive scheme designed fraudulently to obtain the '161 and '154 Patents and willfully to maintain their monopoly power. This scheme included procuring the '161 and '154 Patents by committing fraud and/or inequitable conduct before the PTO, improperly listing the '161 and '154 Patents in the Orange Book, and improperly filing and prosecuting the objectively baseless Patent Litigation against the Generic Manufacturers. Defendants' scheme was designed to delay the introduction of AB-rated, generic versions of Toprol-XL into the market.

112. By their scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to Toprol-XL in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices for their extended-release metoprolol succinate requirements.

113. Plaintiff and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their extended-release metoprolol succinate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust

laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiff and the Class are the proper entities to bring a case concerning this conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for the following:

A. Judgment in its favor and against Defendants, jointly and/or severally, for damages representing the overcharges paid by Plaintiff and the other members of the Class, trebled;

B. Pre- and post-judgment interest; and

C. Costs of suit, including reasonable attorneys' fees.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

Respectfully submitted,

Date: February 6, 2006

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JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
ROCHESTER DRUG CO-OPERATIVE, INC. on behalf of itself and all others similarly situated

(b) County of Residence of First Listed Plaintiff Monroe County, New York
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jeffrey S. Goddess, Rosenthal, Monhait Gross & Goddess, PA, PO Box 1070, Wilmington, DE 19899 (302) 656-4433

DEFENDANTS
ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRAZENECA AB and AKTIEBOLAGET HASSLE

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☒ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Sherman Act, 15 U.S.C. §2. Civil antitrust action in connection with
Brief description of cause: monopolization of market for the drug metoprolol succinate (sold as "Toprol").

VII. REQUESTED IN COMPLAINT:
☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions):
JUDGE Gregory M. Sleet DOCKET NUMBER 06-052; 06-063; 06-071; 06-073

DATE 2/6/06
SIGNATURE OF ATTORNEY OF RECORD
Jeffrey S. Goddess (No. 630) (302) 656-4433

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____